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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,068	01/26/2006	Alan Martin Birch	101160-1P US	8460

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ASTRAZENECA R&D BOSTON
35 GATEHOUSE DRIVE
WALTHAM, MA 02451-1215

EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,068	BIRCH ET AL.	
	Examiner	Art Unit	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18 and 19* is/are allowed.

6)☒ Claim(s) *1,3-10 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/31/06 and 5/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,3-10 and 16-22 are currently pending in the instant application. Applicants have cancelled claim 2 in the amendment filed on May 2, 2007.

I. *Priority*

The instant application is a 371 of PCT/GB04/03364, filed on August 4, 2004 and claims benefit of Foreign Application UNITED KINGDOM 0318464.5, filed on August 7, 2003.

II. *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on May 31, 2006 and May 2, 2007 are in partial compliance with the provisions of 37 CFR 1.97 because of missing English translations or a concise explanation of the relevance. Accordingly, the information disclosure statements have been partially considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election without traverse of Group I in the reply filed on May 2, 2007 is acknowledged. Applicants' request to retain the original definition of variable "r" in claim 1 has been permitted by the Examiner.

Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

IV. Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(1) Claims 1, 3-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The term "prodrug" in the above claims are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1, 3-10 and 17.

(2) Claims 1, 3-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (1) (*See* pages 6 and 7 of the specification), does not reasonably provide enablement for a prodrug of a compound of formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a compound of formula (1) or a pharmaceutically acceptable salt or prodrug thereof.

The state of the prior art

It is the state of the prior art that the term "prodrug" found in the claims is defined as a pharmacological substance (drug) which is administered in an inactive (or significantly less active) form. Once administered, the prodrug is metabolized in vivo into the active compound (<http://en.wikipedia.org/wiki/Prodrug>).

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what prodrugs are being included in the elected invention. The term "prodrug" is discussed on page 7 of

the specification and reads on the following "A prodrug may be used to alter or improve the physical and/or pharmokinetic profile of the parent compound and can be formed when the parent compound contains a suitable group or substituent which can be derivatized to form a prodrug". The only example given of a prodrug is in the general sense of an in-vivo hydrolysable ester.

The breadth of the claims

The breadth of the claims is a compound of formula (1) or a pharmaceutically acceptable salt or prodrug thereof.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with both similar and different structural radicals without any direction as to what structural radical is needed and how different the prodrug can be from a compound of formula (1).

The level of skill in the art is high without showing or guidance as to how to make prodrugs of a compound of formula (1) it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide prodrugs of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the term "prodrug".

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Applicants' claim recites "A compound of the Formula (1), or an in-vivo hydrolysable ester..... thereof." The Specification states:

> An in-vivo hydrolysable ester of a compound of formula (1) containing carboxy or 5 hydroxy group is, for example. A pharmaceutically acceptable ester which is cleaved in the human or animal body to produce the parent acid or alcohol.

The omitted structural cooperative relationship is the "in-vivo hydrolysable ester" of formula (1). Although the specification lists various example of esters, it is unclear how many esters are present and where the esters are located on the structure.

V. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 8:30 AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shawquia Young
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600